

Docket No. MCP-262

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Re application of: Bunick, et al.

Application No.: 09/752,899

Group No.: 1615

Filed: December 29, 2000

Examiner: Cchannavajjala, LS

For: SOFT TABLET CONTAINING DEXTROSE MONHYDRATE

Commissioner for Patents

P.O. Box 1450

Alexandria, VA 22313-1450

**DECLARATION OF PRIOR INVENTION IN THE UNITED STATES
OR IN A NAFTA OR WTO MEMBER COUNTRY
TO OVERCOME CITED PATENT OR PUBLICATION (37 C.F.R. § 1.131)**

PURPOSE OF DECLARATION

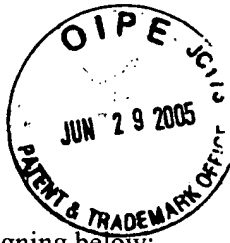
1. This declaration is to establish completion of the invention of this application in the United States of America at a date prior to August 23, 1999, which is the effective date of U.S. Pat. No. 6,495,177 that was cited by the Examiner.
2. The person making this Declaration is Joseph Lubner, a joint inventor.

FACTS AND DOCUMENTARY EVIDENCE

3. To establish the date of completion of the invention of this application, the following attached documents and/or models are submitted as evidence:
Copy of page 101 from notebook number 389.
4. From this document, it can be seen that the invention in this application was actually reduced to practice at least on June 30, 1999.

TIME OF PRESENTATION OF THE DECLARATION

5. This Declaration is submitted prior to final rejection.



DECLARATION

6. As a person signing below:

I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code, and that such willful false statements may jeopardize the validity of the application or any patent issued thereon.

SIGNATURE(S)

7.

Full name of joint inventor Joseph Lubner

Inventor's signature *Joseph Lubner*

Date: 6-23-2005

Country of Citizenship: USA

Residence USA

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PROJECT NO. 0857	DATE OF FIRST ENTRY 6-30-99	BOOK NO. 389	PAGE NO. 101
SUBJECT/PURPOSE			CONTINUED FROM (PAGE)

Purpos Evaluate Eurand APAP

Similar to 369- but use blend of PEG 8000 with PEO 2,000,000 MW

Pharm 6-30-99
replace Aspartame with Sucralose

Step#	Part #	Lot #	Ingredient	mg/tab	Theory g/batch	Actual g/batch	Perf. By
1	M6092		PEO- 2,000,000 MW (Union Carbide)	25	4.17	4.17	<i>OK</i>
	8R01107		PEG 8000	75	12.50	12.50	<i>OK</i>
	501094-5812		Firmenich N&A Orange 57.842/AP 05.51	6	1.00	1.00	<i>OK</i>
	9900540-R		Sucralose	8	1.00	1.00	<i>OK</i>
	9702526		Citric Acid Anhydrous USP Powder	8	1.33	1.33	<i>OK</i>
	142828702		Cerelose Dextrose Monohydrate	457	76.17	76.2	<i>OK</i>
2	180616A		Crospovidone-Polyplasdone XL-10	62.5	10.42	10.42	<i>OK</i>
	7A0082		Eurand APAP	555.5	92.58	92.62	<i>OK</i>
3	3096000	9M00848	Mg Stearate	5	0.83	0.83	<i>OK</i>
TOTAL				1200	200 Batch Size		

Directions

- 1 Add ingredient to plastic bag, close and invert 50 times.
 - 2 Add ingredients to plastic bag and invert 30 times
 - 3 Add ingredients to plastic bag and invert 20 times
- Compress on Betapress using 1 set of 19/32" deep concave

Friability

Press RPM	Compression ms / KN	Comments	Hardness (kp)	Thickness (")	DT-37C Water (min)	Friability First/Last Broke
40	38/10	No Pick - bowl full but center	353	1.52		35/60
		Good meltdown - ingested 5 tablets	1.5-2	1.353		
		Viscous - long chewed	Pharm 6-30-99			

REDACTED COPY

ABOVE ENTRY MADE BY

Joe 21

DATE COMPLETED

6-30-99

WITNESSED BY

DATE

CONTINUED ON (PAGE)

READ AND UNDERSTOOD BY

Joe 21

DATE

11/18/99